

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Bloomberg et al.

Confirmation No.: 4885

Application No.: 10/570,048

Group Art Unit: 1773

International Filing Date: December 12,
2006

Examiner: Ludlow Jan M

For: pH Colour Indicator For Use With Agricultural Compounds

DECLARATION PURSUANT TO 37 CFR § 1.132

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Kelly Tanaka Ph.D., declare as follows:

1. I am a citizen of Canada and currently reside at 323 Riverdale Avenue, Toronto, Ontario, Canada, M4J 1A3.
2. I have been asked to provide this affidavit regarding what a person of ordinary skill would understand to be meant by "red cabbage extract" in the context of U.S. Patent Application Serial Number 10/570,048 ("048 Application"). I have also been asked to provide this affidavit regarding whether it was obvious to use red cabbage extract as a pH indicator in an agricultural composition.
3. I am not receiving any separate or additional compensation for my time spent in preparing this affidavit.
4. It has been explained to me by our patent attorney, and it is my understanding, that the 048 Application is currently pending before the United States Patent and Trademark Office.

5. I have read and am familiar with the 048 Application and the description therein of the pH colour indicator. I have read and have a general understanding of the subject matter recited in the claims of the 048 Application.

6. The 048 Application relates to a class of pH indicators that are suitable for use in agricultural compounds. These indicators are naturally occurring substances, which are used because regulatory bodies are ever more frequently prohibiting the use of chemical pH indicators in compounds which are used for crops and animals. These naturally occurring compounds satisfy the concerns of regulatory bodies.

7. The 048 Application describes three specific types of naturally occurring pH indicator substances -- grape skin extract, red cabbage extract and lichen extract. I have been advised by our patent attorney that the application is now limited to only the use of red cabbage extract.

8. I have been advised that all claims of the 048 Application are currently rejected by the Examiner. As I understand it, the Examiner is stating that there is not sufficient disclosure of the extraction process in the application to explain how the red cabbage extract is made. In other words, the Examiner believes that it is not well known in the art how to obtain red cabbage extract. The Examiner has stated therefore that the application fails to teach persons who might use this technology how to make extract.

9. As I further understand it, the Examiner is stating that the scope of the claims at the end of the application is unclear because the meaning of the term "red cabbage extract" is unclear. In other words, a claim to a concentrate that has a certain percentage by weight of "red cabbage extract" is not clear because the meaning of "red cabbage extract" is not clear. The Examiner is asking for evidence that when the term "red cabbage extract" it would have a clear meaning to persons who might use this technology.

10. Finally, as I further understand it, the Examiner has stated that a concentrate that contains red cabbage extract as the colour indicator, for use with agricultural compounds, is obvious. The Examiner states that because it was known to use methyl red as a colour indicator with agricultural compounds (from Fisher Patent No. 5,278, 132, which I have read), and because red cabbage extract was a known colour indicator for use in detecting bacteria in food substances

(from Freadman Patent No. 6,589,761, which I have read), that it would be obvious to use red cabbage extract, instead of methyl red, as a colour indicator in agricultural compounds.

11. I will address each of these points below.

12. I have a Ph.D. in organic chemistry from the Department of Chemistry at Simon Fraser University. I graduated in 2000. I have an additional 10 years of industrial experience and a comprehensive understanding of colour indicators. I am well versed in the extraction of natural products from plants and have invested a substantial amount of time developing an understanding of these processes. I have been completing laboratory work in an unrelated plant extract process since joining NutriAg Ltd. (the assignee of the 048 Application), where my current title is Carbohydrate Technology Manager.

13. To me, a person of ordinary skill with respect to the 048 Application means someone who would work with and be familiar with the type of technology that is described in this application. With regard to the first point, people working in this area would understand red cabbage extract to mean a liquid extract of cabbage with as much water removed as possible and having a consistent and stable composition of the indicator compounds.

14. Red cabbage extract is purchased from suppliers. I have attached typical spec sheets from two different companies, Colarome Tech Sheet and ROHA (Exhibit "A"). Few companies in North America sell this material. These two companies list the colour value in different units. The optical density, which is a measure of colour strength, can be expressed in different ways. The red cabbage juice concentrate has an optical density of 1600 at a wavelength of 530 nm, at a concentration of 100% (in McIlvaine buffer pH 3.0). It can be equally expressed as E1% 16 or E100% 1600.

15. Thus, the colour values from the two suppliers are the same value. Specifically, Colarome lists a colour value of E100% = 1600, whereas Roha lists their colour as a EV = 1% = 16.

16. I have also attached a statement from Colarome indicating that this is the standard concentration that is used in the industry (Exhibit "B"). These purchased products are typically supplied to the food and beverage industry and as such are of a typical standard.

17. Thus, the term "red cabbage extract" in my opinion, is a term of art that would be understood by persons working in this area to be an extract having as much water removed as possible to result in a stable and consistent composition of indicator compounds. It would be purchased from a supplier, rather than made from scratch.

18. To address the Examiner's view that the invention is obvious, I have attached a word document which has a table of some of the experiments that were tried by the inventors, with different natural pH indicators (Exhibit "C"). Of particular importance is the fact that when the red grape extract was tested the indicated colour appeared to "fade" over time and was not useful. What was likely happening was the breakdown of the active anthocyanins within the extract. There is evidence in the literature to suggest that non-acylated anthocyanins are less stable, and I have attached a journal article to support this claim (Exhibit "D"). These less stable non-acylated type are typically found in grapes.

19. Only one concentration of the lichen extract was tested and the colour intensity was too weak for it to be of use. Given the high cost of procuring this material, it was not feasible to use it as a pH indicator.

20. Unexpectedly, the red cabbage extract worked very well in comparison to the grape extract, however, we had to use a very high concentration of this red cabbage extract to arrive at a colour end point that had utility in agricultural applications, which was not expected.

21. There is no way to predict which natural extracts will be useful and which ones won't—it is a process of trial and error to find a reproducible and reliable extract that will work, as evidenced by the data that we have presented. The lichen extract was too weak to be useful, and the grape seed extract was not stable enough.

22. In my opinion, the replacement of the synthetic indicator used by Fisher (methyl red) by a natural extract from red cabbage suggested by Freadman (red cabbage extract) is not obvious for several reasons.

23. First, I do not believe that a patent that relates to detecting bacteria in food has anything to do with using pH indicators in agricultural compounds that are used on crops, soil, or animals. Therefore, I do not believe that anyone working with the type of agricultural compounds that are discussed in the 048 Application would look at the Freadman patent.

24. Second, it would be obvious to substitute a simple chemical pH indicator like methyl red, which has a defined composition and known physicochemical properties such as stability, with another simple chemical pH indicator that has a defined composition and known physicochemical properties. The same cannot be said for substituting a simple chemical pH indicator with red cabbage extract, which is much more complex than a single molecule.

25. This is true especially when the technologies are so very different.

26. Third, a red cabbage extract is complex and can contain a number of other components that will have a beneficial or deleterious effect on its ability to act in the types of agricultural compounds that are discussed in the 048 Application. The use of red cabbage extract in agricultural applications, when it was known that methyl red, a simple chemical compound of known stability could be used in similar applications, was simply not a predictable result.

27. For these reasons, it is my opinion that the use of red cabbage extract was not at all obvious given that methyl red had been used for agricultural applications.

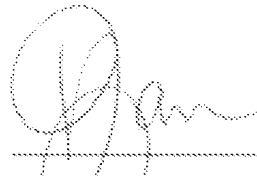
28. I have attached a document from one of our customers in California, California Ag Solutions (Exhibit "E"). It should be noted that "BB5 Natural" referred to in this letter is the pH indicator product sold by NutriAg Ltd., which contains the red cabbage extract indicator. NutriAg's original product, "BB5", is not allowed to be used in California because it contains a synthetic indicator, allowing therefore for the excellent positioning of a unique product like BB5 Natural. The letter from NutriAg's customer attests to the fact that the invention described and claimed in the 048 Application has satisfied the needs of farmers in California to have access to a natural based colour indicator that meets the stringent requirements of California regulations.

29. NutriAg Ltd.'s BB5 Natural is a commercially successful product that has filled a void in the marketplace. NutriAg Ltd. expects the market will only increase with time, and wants to protect this product from competition by obtaining patent protection for it.

30. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code.

and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: Nov 24, 2011



Kelly Tanaka, Ph.D.

EXHIBIT A

OF DECLARATION OF KELLY TANAKA, PH.D.



Technical Information Sheet

RED CABBAGE JUICE COLOR CONCENTRATE

XCR-900L

1. Product Description

Names: Red cabbage juice color concentrate or red cabbage anthocyanins.

Description: Dark (almost black) viscous liquid.
The coloring principles of red cabbage *i.e.*, anthocyanins, provide a red color to slightly acid products.
A food additive of natural origin that may be used as coloring agent in foods (Canada Food and Drugs Act and Regulations and United States Code of Federal Regulations: 21 CFR 73.260); may also be used as an inert ingredient in pesticides (US Environmental Protection Agency, 40CFR Part 180 [OPP-2004-0361, FRL-7711-7]).

Ingredients: Red cabbage juice, propylene glycol (18%), citric acid (2%).

Available formats: 20 kg, 200 kg

2. Physical Properties and chemical Properties

Density: 1.2 ± 0.1 at 22-25°C

Color Units*: at least 1600 (w/w)

* (absorbency measured at 535 nm in McIlvaine buffer at pH 3 x dilution factor)

3. Recommended usage level: 0.02 - 0.2 % (w/w)

4. Shelf Life and Storage Conditions

Up to 12 months under refrigeration (4°C) in the original container. Close tightly after use.

5. California Proposition 65

This product does not contain chemicals known to the State of California to cause cancer or reproductive toxicity as per listed in Proposition 65.

6. Allergen Statement

This product does not contain the following known allergens or derivatives thereof: peanuts, tree nuts, sesame, milk, eggs, fish, shellfish and mollusks, soy, wheat or, sulphites.

7. Production Code

Description: 1st number indicates the last number of the year of production, followed by 2 letters indicating the month of production, followed by 2 numbers for the date and 3 numbers for the production of that day (of any product, coloring or flavorings). Example: « Lot# 6JN27001 » indicates that the product came from the first production on June 27th, 2006.



PRODUCT SPECIFICATION

Product Code	Product Name
110020503111	NATRACOL RED CABBAGE EXTRACT WSL

Description

Red cabbage extract is a dark red liquid produced by color extraction and concentration of the red cabbage juice.

Appearance

Dark purple red liquid with characteristic smell.

Specification

Colour Strength* EV	10 ± 0.5
pH	2 – 4
Solubility	Soluble in water
Additives	Citric acid


Camorian
622 Lyons Lane, Suite 100
Oakville, Ontario, Canada L4J 5V1
Phone: 905.331.3177 Fax: 905.331.9448
E-mail: info@camorianchem.com, sales@camorianchem.com

Packing :

10 lbs & 55.5 lbs aseptic packing. Customer specific pack sizes available upon request

Labelling:

Labelling displays product name, lot number, net weight, gross weight and other information and marks specified by the customer.

Storage:

Store in airtight containers at 4 deg C, protected from light and oxidation. It is recommended to use the product at once if the container is opened.

Shelf Life:

12 months from the date of manufacture for unopened packs under specified storage condition.

Handling:

Avoid contact with skin and eyes. Mix well before using the product.

Certificates:

MSDS and Certificate of analysis accompany the consignment.

Methods:

*107

This information is to our knowledge true and correct and presented in good faith. No warranty, guarantee or freedom from patent infringement is implied or intended. This information is offered solely for your consideration and verification. It is our check the local legislation regarding application of the product.

EXHIBIT B

OF DECLARATION OF KELLY TANAKA, PH.D.



St-Hubert, October 18th 2011

Mr. Martin Bloomberg
NutriAg Ltd.
39 Gail Grove
Toronto, Ontario
CANADA M9M 1M5

Subject: Industry Standard for Red Cabbage Juice Concentrate

Dear Mr. Bloomberg,

This letter is to confirm that normal industry standard for color value of Red Cabbage Juice Concentrate is established as follows:

Color Value: E 100% / ph 3.0 / 530 \pm 5nm \geq 1600 Optical Density

The industry standard applies to all formulations of Red Cabbage Juice Concentrate manufactured by Colarôme Inc.

Best regards,

Colarôme Inc.

Robin Côté
President

EXHIBIT C

OF DECLARATION OF KELLY TANAKA, PH.D.

Extract	Quantity used in formulation	Amount of indicator	Colour at end point (scale of 1-10)	30 day stability	60 day stability
	kg of indicator/ total kg of concentrate				
Grape skin extract 400 (Rudolf Keller)	50 kg/1000kg	0.07%	1	Moderately stable	Unstable*
Grape skin extract 400 (Rudolf Keller)	100 kg/1000kg	0.13%	2	Moderately stable	Unstable*
Grape skin extract 400 (Rudolf Keller)	150 kg/1000kg	0.20%	4	Moderately stable	Unstable*
Red cabbage concentrate XCR-900L (Colarome)	15 kg/1000kg	0.075%	1	Stable	Stable
Red cabbage concentrate XCR-900L (Colarome)	25 kg/1000 kg	0.125%	2	Stable	Stable
Red cabbage concentrate XCR-900L (Colarome)	50 kg/1000 kg	0.25%	4	Stable	Stable
Red cabbage concentrate XCR-900L (Colarome)	100 kg/1000 kg	0.5%	8	Stable	Stable
Red cabbage concentrate XCR-900L (Colarome)	275 kg/ 1000 kg	1.38%	>10	Stable	Stable
Lichen	0.7 kg/1000 kg	0.07%	1	stable	stable
Methyl red	0.7 kg/1000 kg	0.07%	10	stable	Stable

*The colour appeared to fade overtime. The literature indicates that grape anthocyanins are not as stable at lower pH.

EXHIBIT D

OF DECLARATION OF KELLY TANAKA, PH.D.

EXHIBIT E

OF DECLARATION OF KELLY TANAKA, PH.D.

From Discovery to Results!

California
Ag Solutions

November 22, 2011

Mr. Matt Lucas
NutroAg USA
PO Box 696
Hilmar, CA 95324

Dear Mr. Lucas:

I am writing to confirm the importance of BB5 Natural as a highly effective, safe, and economical product for California farmers to solve their toughest pest problems.

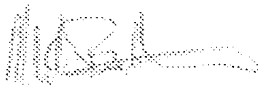
Water used as a carrier can vary dramatically in hardness and pH from source to source and from month to month. BB5 Natural allows farmers to easily overcome this challenge with its unique color indicator. By watching the color of the water, farmers can add the correct amount of BB5 Natural for every situation.

Since BB5 Natural allows to easily adjust hardness and pH, farmers can confidently use the lowest recommended label rates of pesticides and still expect the best results possible. This in turn greatly reduces the pounds of pesticides that are applied to fields every year. BB5 Natural is a component to reducing the environmental impact of pesticides.

BB5 Natural allows California farmers to enjoy the benefits of regular BB5 with a natural based color indicator that meets the stringent requirements of California regulations. Without the natural based color indicator, this incredible tool would not be available to California farmers.

We look forward to continuing to help farmers with their water and spray challenges with BB5 Natural. This unique, one of a kind product is a sustainable solution for California farmers and environment.

Best regards,



Monte Bottens, CCA

California Ag Solutions, Inc. 4746 W Jennifer Ave Ste 104 Fresno, CA 93722
monte@calagsolutions.com 559-694-1592 mobile 559-277-0940 fax

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Application No.: 10/570,048
Office Action Dated: May 26, 2011

PATENT